

## **Consent Form (English)**

### **Title:**

The effect of esophageal sparing IMRT on patient-reported dysphagia outcomes in patients with non-small cell lung cancer treated with radical radiotherapy with or without chemotherapy.

### **Short title:**

The effect of esophageal side effects on patients receiving esophageal-sparing IMRT when given radiotherapy with or without chemotherapy in lung cancer patients.

### **Introduction:**

We invite you to participate in this study titled “Impact of esophageal-sparing IMRT on outcomes in patients with swallowing difficulties (dysphagia) in non-small cell lung cancer patients receiving radical radiotherapy with or without chemotherapy.”

You are being invited to participate in this study because you have been diagnosed with lung cancer and will be receiving radiotherapy treatment. The details of this study are presented in this document.

Please read this information carefully. If you have any questions or would like to know more, please feel free to ask.

### **Research Objectives**

When patients with lung cancer are given radiotherapy, the normal organs inside the chest receive high doses of radiotherapy. Due to this dose, patients experience various side effects. The esophagus is one of these organs. Therefore, radiation-induced swallowing difficulties and heartburn are among the common acute side effects of radiotherapy.

IMRT (Intensity Modulated Radiotherapy) is a modern treatment method where the radiation dose to these organs is reduced with the help of computerized modern planning. Through the technique that we are going to use (esophageal sparing IMRT), we will try to keep the esophagus further away from the radiation exposure, which will help to reduce these symptoms further.

During our study, patients receiving radiation will be assessed on a weekly basis. Swallowing difficulties reported by both the physician and the patient will be recorded each week during radiation at the review clinic.

This study will not give you any additional or new treatments. We will attempt to determine the rate of patient-reported and physician-referred radiation-related moderate to severe swallowing difficulties in patients receiving concurrent chemoradiotherapy, sequential chemoradiotherapy, or radical radiotherapy alone for non-small cell lung cancer.

We will also try to find out how long it takes for patient-reported moderate to severe swallowing difficulties to develop in patients undergoing radiotherapy for lung cancer.

As part of this study, we would like to collect more detailed information about the side effects you experience during treatment. We will do this in 2 ways—

- 1) Through a questionnaire, which you will be asked to complete every week during treatment, and
- 2) Another form, which the doctor will fill out when he sees you every week.

### **What do I need to do to participate?**

1. First, we will ask you to read and understand this consent form and ask if you have any questions about the procedure.
2. Your radiotherapy will be planned through a CT scan.
3. We will calculate the best possible dose using a computer system.
4. Every week during radiotherapy, a doctor will ask you about the side effects you are experiencing. You will be given some questions, where you will have to answer about difficulty swallowing and heartburn that you may have during treatment.
5. Once your treatment is complete, you will be followed up at regular intervals.

### **What are the participation options?**

You can decide not to participate in this study. This will not affect your treatment.

**What are the potential risks?**

We do not anticipate any additional risks in the study.

**How much does it cost to participate?**

There is no additional cost for this. You will not be asked to pay any additional money to participate in the study.

**Will any money be refunded?**

There are no plans to provide any refunds as part of this research.

**What are the potential benefits?**

This study will help us identify the incidence, duration, and severity of radiation-related swallowing difficulties caused by the use of esophageal sparing IMRT, which will pave the way for timely assessment, improved supportive care and may reduce the incidence of treatment-related toxicity.

**Will my information be kept confidential?**

Yes. The information you provide will be stored securely and anonymously at Tata Medical Centre, accessible only to your doctor and nurses. It will not be used to identify you or reveal your identity and will not be disclosed without prior consent.

**Injury Compensation:**

Since this study does not include any new interventions, no compensation will be provided for side effects, the cost of treating side effects will only be borne by the patients.

**Participation**

Participation in the study is voluntary. If you do not wish to participate, you may withdraw at any time. Whether or not you participate in the study, you will receive appropriate treatment. You will be given a copy of this participant information and consent form for your records.

**Contact**

Tata Medical Center Phone: 033-6605-7000

If you have any questions about the study at any time, you can contact the researchers in the following ways.

Dr. Tapesh Bhattacharya	Dr. Moses ArunSingh	Dr. Urvashi Thakur
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**Address:**

Tata Medical Center, 14 Mar (East-West), Newtown Action Area 3.

Phone: 033-6605-7000, 033-6605-7404.

For any queries, the Tata Medical Centre Institutional Review Board (TMC-IRB) can be contacted at 03366057579. The Director of TMC is the appellate authority.

**Consent**

I understand the above information and agree to participate in this trial.

Patient's signature: \_\_\_\_\_

Name: \_\_\_\_\_

Investigator's signature: \_\_\_\_\_

Name: \_\_\_\_\_

Date: \_\_\_\_\_

Witness signature:

\_\_\_\_\_ Name: